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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,661	02/20/2002	Kerry Kulowski	1221.001US1	6625

7590 05/06/2003

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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/06/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary <i>File Copy</i>	Application No.	Applicant(s)	
	10/082,661	KULOWSKI ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9 and 17-18, drawn to a method for “producing one or more biocatalysts or a combinatorial array of biocatalysts”, classified variously in 435, subclass 6, DIG 45-46.
 - II. Claims 10-16, drawn to a method for “the screening of cells having at least two distinct biotransforming catalysts combined therein, classified variously in class 435, subclass 6, DIG 2-5.
2. The inventions are distinct, each from the other because of the following reasons:
3. Groups I and II are directed to separate and patentably distinct methods. The methods are different because they use different steps, require different reagents and/or will produce different results. In the instant case, the method of Group II employs steps and reagents for “screening” a library, whereas the method of Group I is drawn to “producing” a library. Consequently, examining Groups I and II together will require searching different reagents, different method steps, and different resulting outcomes, which will fall under different US classification numbers

Art Unit: 1639

i.e., a method for producing a library is classified in 435, DIG 45-46, whereas a method of screening a library is classified in 435, DIG 2-5. Therefore, searching Groups I-II together would represent an undue search burden. In addition, art anticipating or rendering obvious Group I would not render obvious Group II, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents. Therefore, Groups I and II have different issues regarding patentability and enablement and represent patentably distinct subject matter.

4. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

5. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-II. Election is required as follows.

6. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of host cell (see claim 1)

Applicant must elect, for the purposes of search, a single species of host cell e.g., *streptomyces lividans* (see specification, page 10).

Art Unit: 1639

Subgroup 2: Species of biotransformation genes (see claim 1)

Applicant must elect, for the purposes of search, a single species of biotransformation genes e.g., PikC (see specification, page 10).

Subgroup 3: Species of number of biotransformation genes into the host cell (see claim 1)

Applicant must elect, for the purposes of search, a single species of number of biotransformation genes into the host cell e.g., applicants must pick the number of biotransformation genes (e.g., see specification, Table 1 wherein three genes were used, please indicate the gene type for each of the three genes i.e., **DO NOT** just put down gene 1, gene 2, gene 3, see subgroup 2 above).

Subgroup 4: Species of chemical substrate (see claim 1)

Applicant must elect, for the purposes of search, a single species of chemical substrate e.g., see circled structure on page 14 of the specification. Furthermore, applicant must show all atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations like R^1 , R^2 , etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

Subgroup 5: Species of biocatalyst (see claim 1)

Applicant must elect, for the purposes of search, a single species of biocatalyst e.g., monooxygenase (see specification, page 5).

Subgroup 6: Species of number of biocatalysts (see claim 1)

Applicant must elect, for the purposes of search, a single species of number of biocatalysts (e.g., see specification, table 1 wherein seven biocatalysts were produced according to the $2^n - 1$ formula).

Subgroup 7: Species of chemical functional group (see claim 2)

Applicant must elect, for the purposes of search, a single species of chemical functional groups i.e., applicant must elect a "representative" product, wherein the functional group is clearly shown (see scheme 1, page 14). Furthermore, applicant must show all atoms and bonds that are necessary the product that contains the chemical functional group and indicate where the chemical functional group is within the product. Applicant should NOT use general notations like R^1 , R^2 , etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

Art Unit: 1639

Subgroup 8: Species of reactions (see claim 4)

Applicant must elect, for the purposes of search, a single species of reactions. Please pick from claim 4.

Subgroup 9: Species of functional group addition of groups capable of providing catalysis (see claim 5)

Applicant must elect, for the purposes of search, a single species of functional group addition of groups capable of providing catalysis.

Subgroup 10: Species of method steps (see claims 1 and 17)

- A. Method steps of claim 1
- B. Method steps of claim 17

Applicant must elect, for the purposes of search, a single species of method steps for producing the biocatalysts from the list above.

7. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 10 is generic.

Subgroup 1: Species of cells (see claim 10)

Applicant must elect, for the purposes of search, a single species of cells e.g., *streptomyces lividans*.

Subgroup 2: Species of at least two distinct biotransformation catalysts (see claim 10)

Applicant must elect, for the purposes of search, a single species of at least two distinct biotransformation catalysts e.g., #1 is monooxygenase; #2 is methyltransferase, etc.

Subgroup 3: Species of chemical compound within each well (see claim 10)

Applicant must elect, for the purposes of search, a single species of compound within each well. If more than one compound is used, applicant must elect a "representative" example. Furthermore, applicant must show all atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations

Art Unit: 1639

like R^1 , R^2 , etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. See page 14 of the specification for examples.

8. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 12 and 13 below).
9. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.
10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered NON RESPONSIVE unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

15. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1639

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an “action on the merits” for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

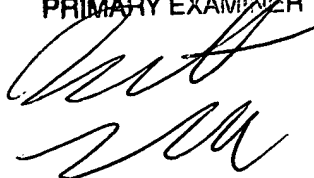
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
April 29, 2003

BENNETT CELSA
PRIMARY EXAMINER



Application/Control Number: 10/082,661

Page 9

Art Unit: 1639